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In the Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG,
COMMISSIONER OF FOOD AND DRUGS, PETITIONER

v.

COMMUNITY NUTRITION INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE PETITIONER

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QUESTION PRESENTED

Whether the Food and Drug Administration is required to regulate unavoidable "added" poisonous or deleterious substances in food by means of formal rulemaking pursuant to 21 U.S.C. 342(a)(2)(A), rather than by case-by-case adjudication pursuant to 21 U.S.C. 342(a)(1).

PARTIES TO THE PROCEEDING

The petitioner is Frank Young, Commissioner of Food and Drugs. The respondents are the Community Nutrition Institute, Public Citizen, and Linda S. Bardot.

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BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-16a) is reported at 757 F.2d 354. The May 1, 1985, order amending the court of appeals' opinion (Pet. App. 17a) and the opinion of the district court (Pet. App. 21a-34a) are unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. 35a) was entered on March 26, 1985. A petition for rehearing was denied on May 23, 1985 (Pet. App. 18a). By order dated August 13, 1985, Justice Brennan extended the time within which to file a petition for a writ of certiorari to and including October 20, 1985. The petition was filed on October 18, 1985, and was granted on December 9, 1985. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Sections 402(a), 406, and 701(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a), 346, and 371(e), and 21 C.F.R. 509.6(b)-(c) are reproduced in an appendix to this brief. App., *infra*, 1a-5a.

STATEMENT

A. Introduction

This case concerns the procedures that the Food and Drug Administration (FDA) must employ in regulating the presence in food of any added poisonous or deleterious substance that is required in the production of the food or that cannot be avoided by good manufacturing practices. Specifically at issue here are "aflatoxins," a group of chemically-related substances produced as natural by-products of the growth of certain common molds on corn and other crops. Aflatoxins exhibit cancer-producing properties in some species of experimental animals, and epidemiological studies on certain population groups in Southeast Asia and Africa indicate that direct consumption of aflatoxin-containing foods may also be associated with primary liver cancer in humans. J.A. 35-37, 169, 203; Pet. App. 3a. However, these studies cannot identify all potential causes of the disease (J.A. 214), and there is no direct evidence that aflatoxin causes primary liver cancer in man. J.A. 35, 46. Data from the National Center for Health Statistics on deaths due to such cancer from all sources in the United States do not show an increased incidence in areas where aflatoxin contamination is an annual problem. J.A. 214, 218-221.

Aflatoxins may contaminate foods whenever environmental conditions are such as to favor the growth of the producing molds. Favorable growth conditions often exist naturally in the field where susceptible crops are growing. Such conditions also can be created when crops are improperly stored. See J.A. 207-208. Human intervention can prevent the problem in the latter situation,

but preventative action is largely ineffective in the case of field contamination, because the contamination occurs before or during harvest. Thus, complete elimination of aflatoxin from susceptible commodities, such as corn, cottonseed, peanuts, and tree nuts, is not currently possible. See J.A. 39, 43, 44, 208; 39 Fed. Reg. 42748 (1974). Moreover, residues of aflatoxin can appear in the edible tissues, eggs, and milk of animals fed aflatoxin-contaminated corn, cottonseed, and other feeds, and there is no known method for removing aflatoxin residues from such products. J.A. 207. For all these reasons, the FDA has treated aflatoxin as a poisonous or deleterious substance and has taken steps to limit human and animal exposure to aflatoxin-tainted food to the greatest extent feasible. 39 Fed. Reg. 42749 (1978); J.A. 187, 207.

Since the enactment of the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938, 21 U.S.C. 301 *et seq.*, the Commissioner of Food and Drugs, as the designee of the Secretary,[1] has regulated the amount of substances like aflatoxin principally by using publicly available prosecutorial guidelines that the FDA terms "action levels."[2] These action levels announce the amount of a particular added poisonous or deleterious substance that the FDA regards as resulting in adulteration under Section 402(a)(1) of the FDCA, 21 U.S.C. 342(a)(1). Food containing such a substance in excess of the action level is subject to an enforcement action by the United States. In this case, the court of appeals upset this longstanding administrative construction of the FDCA, holding that the FDA may not proceed by means of action levels but must instead set "tolerances" by time-consuming and burdensome formal rulemaking procedures.

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[1] Pursuant to Section 701(a) of the FDCA, 21 U.S.C. 371(a), and under the authority delegated to him by the Secretary (21 C.F.R. 5.10), the Commissioner of Food and Drugs is authorized to enforce the FDCA.

[2] The FDA's action levels have been publicly available since 1972. Prior to that time, the agency's action levels were generally treated as confidential internal policy matters. See 37 Fed. Reg. 6497 (1972). Current action levels are reprinted at J.A. 148-168.

B. The Statutory and Regulatory Framework

1. *The Statutory Definition Of "Adulterated" Food.* The FDCA prohibits the shipment in interstate commerce of "adulterated" food. 21 U.S.C. 331. A food is generally deemed to be "adulterated" due to the presence of a poisonous or deleterious substance, whether it is inherent in the food or is "added" to it,[3] if any one of three conditions is met. See 21 U.S.C. 342(a)(1) and (2)(A).[4] *First*, a food is deemed adulterated under the first clause of Section 402(a)(1) of the FDCA, 21 U.S.C. 342(a)(1), if it contains an added poisonous or deleterious substance "which may render it injurious to health."[5] *Second*, if a substance is inherent in a food (*i.e.*, is not "added"), then, under the second clause of Section 402(a)(1), food containing that substance is adulterated if the substance renders the food "ordinarily * * * injurious to health."[6] *Third*, a food is adulterated under Section 402(a)(2)(A), 21 U.S.C. 342(a)(2)(A), if it contains any "added poisonous or added deleterious substance * * * which is unsafe within the meaning of" Section 406, 21 U.S.C. 346. Aflatoxin fits within this last provision (as well as the first one); it is not an inherent constituent of food since it is added by mold. J.A. 34-35.

[3] The term "added" is not defined in the FDCA. The FDA's regulations define an "added" poisonous or deleterious substance as one that "is not a naturally occurring * * * substance" (21 C.F.R. 109.3(d), 509.3(d)), and, in turn, define a "naturally occurring poisonous or deleterious substance" as "a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination" (21 C.F.R. 109.3(c), 509.3(c)). See also 42 Fed. Reg. 52814-52816 (1977); 39 Fed. Reg. 42743-42744 (1974); J.A. 13-15, 55-56, 56-57, 61-63.

[4] The general adulteration standard set forth in Section 402(a)(1) is supplemented by other provisions containing more specific safety standards for pesticides (see 21 U.S.C. 346a), food additives (see 21 U.S.C. 348), color additives (see 21 U.S.C. 376), and new animal drugs (see 21 U.S.C. 360b).

[5] See *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 161 (1958); *United States* v. *Coca Cola Co.*, 241 U.S. 265, 277, 283 (1916); *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914).

[6] See *Continental Seafoods, Inc.* v. *Schweiker*, 674 F.2d 38, 41 (D.C. Cir. 1982); *United States* v. *Anderson Seafoods, Inc.*, 622 F.2d 157, 159 (5th Cir. 1980).

Section 406 of the FDCA defines when a food with an added poison is "unsafe" within the meaning of that provision. The first clause of Section 406 provides that any added poisonous or deleterious substance renders the food unsafe unless its presence "is required in the production thereof or cannot be avoided by good manufacturing practice." Aflatoxin falls within this exception (see J.A. 187, 207), and food containing aflatoxin is therefore not rendered "unsafe" by this clause. However, Section 406 goes on to state:

> [W]hen such substance is so required or cannot be so avoided, the Secretary [of Health and Human Services] shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of [Section 342(a)(2)(A)].

Section 406 further provides that, while a regulation is in effect, food containing such a substance is not adulterated under Section 402(a)(1).

2. *The FDA's Use Of "Action Levels" And "Tolerances."* For nearly a half-century, the FDA has construed these provisions as allowing it to regulate substances such as aflatoxin either by exercising its prosecutorial discretion to bring enforcement actions under Section 402(a)(1), 21 U.S.C. 342(a)(1), or by issuing regulations ("tolerances") via formal rulemaking pursuant to Sections 406 and 701(e), 21 U.S.C. 346 and 371(e). If the FDA elects to proceed under Section 402(a)(1), the government must establish in an enforcement proceeding that the level of the added substance present may render the food injurious to health. This is the option that the FDA has used with respect to aflatoxin, and the FDA has

adopted an "action level" to aid in the exercise of its prosecutorial discretion. J.A. 150. In the alternative, the FDA may promulgate a tolerance under Section 406. Once a tolerance is in effect, the government in an enforcement proceeding need only establish that the tolerance has been exceeded; it need not adduce independent evidence that the food may be injurious to health. See 21 U.S.C. 342(a)(2)(A) and 346. Therefore, the use of action levels or tolerances affects only the government's elements of proof in an enforcement action. In either case, the contaminated food is subject to seizure (see 21 U.S.C. 334) and the person responsible for shipping the contaminated food in interstate commerce may be enjoined from causing such shipment (see 21 U.S.C. 332) and subjected to criminal sanctions (see 21 U.S.C. 333).

The FDA considers the same factors—*i.e.*, those set forth in 21 U.S.C. 346—in setting both action levels and tolerances. 21 C.F.R. 109.6 (human food); 21 C.F.R. 509.6 (animal feed).[7] However, the procedures employed in promulgating action levels differ significantly from those required for the issuance of tolerances. Action levels are not considered to be subject to the notice-and-comment rulemaking procedures of the Administrative Procedure Act.[8] Nonetheless, the FDA does publish a notice in the *Federal Register* announcing the new level and the availability of all the relevant data, and it invites public comment. See 21 C.F.R. 509.4(b)(2); 42 Fed. Reg. 52817 (1977).

By contrast, 21 U.S.C. 346, in conjunction with 21 U.S.C. 371(e), prescribes a formal and complicated pro-

[7] These factors include (1) the level necessary to protect the public health, (2) the extent to which the substance is unavoidable, (3) the effect of other poisonous or deleterious substances on the public health, and (4) the ability of analytical methods to detect and quantify the substance when it is discovered in food. 21 C.F.R. 109.6, 509.6; J.A. 21-22. The FDA considers the overall economic impact of the permitted level in connection with the second factor. See 42 Fed. Reg. 52816 (1977).

[8] Respondents challenged this practice below, but the court of appeals did not address the point (Pet. App. 2a).

cedure for the issuance of regulations setting, amending, or repealing tolerances for substances whose addition to food is required or unavoidable. The FDA must publish a proposed tolerance for public comment. 21 U.S.C. 371(e)(1). After evaluating the comments, the FDA must publish a "final order" to which objections can be filed, along with requests for a formal trial-type administrative hearing. *Ibid.* The filing of an objection accompanied by an adequate request for a hearing stays the effectiveness of the tolerance pending further notice in the *Federal Register* and the hearing itself (21 U.S.C. 371(e)(2)), at which "any interested person may be heard in person or by representative" (21 U.S.C. 371(e)(3)). Finally, following the completion of the formal administrative proceeding, including an initial decision by an administrative law judge and any subsequent appeal to the Commissioner of Food and Drugs, the FDA must issue an order setting forth "detailed findings of fact" and establishing the tolerance. *Ibid.* Except in emergencies, the regulation may not take effect until 90 days after the Commissioner's decision (*ibid.*), which is subject to judicial review in the court of appeals (21 U.S.C. 371(f)). In short, 21 U.S.C. 346 and 371(e) mandate a formal rulemaking procedure properly characterized as one of the more elaborate under which any federal agency must operate. See generally R. Merrill & P. Hutt, *Food and Drug Law* 895-896 (1980).

In determining whether to issue informal action levels or formal tolerances in a particular case, the FDA takes these procedural differences into account. Because of the exhaustive procedures necessary to establish a new tolerance or to modify an existing one, the FDA generally establishes tolerances only when their lifespan is expected to be relatively long. Accordingly, the FDA's regulations provide for the use of action levels in dynamic circumstances, *i.e.*, when it is impracticable to set tolerances. See 21 C.F.R. Pt. 109 (human food); 21 C.F.R. Pt. 509 (animal feed); J.A. 21, 68. The FDA uses action levels rather than tolerances when the extent to

which a substance is unavoidable may change yearly, when changes in the capabilities of good manufacturing practices are expected, or when current toxicological data are scanty or conflicting but the results of ongoing studies might provide significant new data or other information that would render a tolerance obsolete. 21 C.F.R. 109.6(b)-(c), 509.6(b)-(c); J.A. 21, 68-70. For instance, the FDA has used action levels to regulate the presence of aflatoxin in corn because the level of aflatoxin in corn varies from region to region, and within regions, from year to year. See J.A. 223-224. In these circumstances, a tolerance would be outdated shortly after its adoption. See J.A. 68.[9]

3. *The Exemption Process.* The FDA has recognized that in some circumstances the public interest may justify allowing certain food containing a substance in an amount in excess of an action level to be marketed. The FDA's regulations therefore allow the Commissioner to refrain from recommending enforcement action (*i.e.*, to grant an "exemption") in such circumstances. 21 C.F.R. 109.8(a)(1), 509.8(a)(1). The FDA has stated that an exemption will be granted only where "a large amount of food is contaminated, resulting in a substantial adverse impact on the national food supply, and all available toxicological data indicate that no significant health hazard is involved." 39 Fed. Reg. 42746 (1974); J.A. 24. An exemption applies only to the specific parties to whom it is granted and only to the particular food covered, and lasts only for a specified period of time. *Ibid.*

In 1965, the FDA set an action level for aflatoxin in human food and animal feed at 30 parts per billion (ppb).

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[9] See also *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149, 153 (5th Cir. 1979) ("[t]he statute does not demand rigid and permanent fixity in the numbers game, mainly because our social policies and scientific knowledge about dangerous food are not themselves steady and static"); *United States* v. *Goodman*, 486 F.2d 847, 854 (7th Cir. 1973) (finding that an in-depth consideration of tolerances for DDT when DDT levels in the environment were in a state of flux would be "virtually meaningless").

J.A. 37. The FDA reduced the action level to 20 ppb in 1969, and it has since remained at that level. *Ibid.*; *id.* at 135, 169, 170; Pet. App. 22a. However, in 1980 the levels of aflatoxin in corn harvested in several states were unusually high. In October and November 1980, in response to requests from Virginia, North Carolina, and South Carolina, the FDA temporarily increased to 100 ppb the action level for aflatoxin-contaminated corn harvested in those states that was intended for feeding to mature, non-lactating beef cattle, swine, or poultry. The agency also permitted blending (mixing) of corn containing more than 20 ppb aflatoxin with untainted corn to achieve a level of up to 100 ppb aflatoxin. The FDA found that, under the terms and conditions of the exemptions, the feed corn was safe for consumption and that the destruction or diversion of the feed would have resulted in a substantial adverse effect on the national food supply.[10] The exemptions were conditioned upon full

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[10] An FDA study, "Aflatoxin-Contaminated Corn, Limited Exemptions from Prohibition of Interstate Shipment and Blending, Assessment of Safety and Impact on the National Food Supply" (Dec. 1980) (J.A. 202-211), concluded that the largest portion of corn containing aflatoxin that was ingested by food-producing animals is eliminated in excreta. *Id.* at 203. Although residues of aflatoxin may be found in the edible tissues of those animals under certain circumstances, so long as the level of aflatoxin in corn fed to the animals identified in the text did not exceed 100 ppb, the level of aflatoxin in their edible tissues would not exceed 0.1 ppb, the lowest level that can consistently be identified and measured in tissues by available analytical methods. *Id.* at 203-206. The FDA thus concluded that the meat and eggs from animals eating corn containing 20-100 ppb aflatoxin were "safe" for consumption within the meaning of 21 C.F.R. 509.8, *i.e.*, that "all available toxicological data indicate that no significant health hazard is involved." 39 Fed. Reg. 42746 (1974).

In 1978, responding to a similar situation, the FDA temporarily authorized the blending of corn containing more than 20 ppb aflatoxin with untainted corn to achieve a level of up to 20 ppb aflatoxin and the subsequent interstate shipment of the blended corn. See 43 Fed. Reg. 14122 (1978). In 1983, the FDA allowed corn containing aflatoxin not exceeding 100 ppb to be shipped in interstate commerce for use as feed for certain animals, on the

compliance by the states and the affected industries with detailed control plans designed to ensure that the terms of the exemptions were satisfied. The FDA's decision not to recommend enforcement action was contingent upon such full compliance. See 46 Fed. Reg. 7447 (1981); J.A. 24, 114-122, 131-132, 189-190, 196-197, 199-201; Pet. App. 25a-26a. These exemptions, which expired on January 1, 1982, gave rise to this lawsuit. Pet. App. 25a, 26a.

C. The Proceedings Below

1. *The District Court's Decision.* Respondents (two public interest groups and a consumer) brought this suit in the United States District Court for the District of Columbia, challenging the FDA's regulation of aflatoxin.[11] Respondents did not allege that the FDA's 20 ppb action level was insufficient to protect the public health or had led to any serious health problem, that formal tolerances were necessary to protect the public health, or that the FDA was not adequately enforcing the FDCA (J.A. 109-112 (complaint)). Rather, they claimed (1) that the FDA should be ordered to adopt a formal tolerance for aflatoxin pursuant to Section 406, 21 U.S.C. 346, rather than to use an informally implemented action level, (2) that the action level, in the alternative, should be made subject to the notice-and-comment provisions of the Administrative Procedure Act, and (3) that the 1980 exemptions to the FDA's action level were contrary to law. J.A. 109-112 (complaint); see also *id.* at 169-171, 225-226.

The district court granted summary judgment in favor of the FDA on all three issues (Pet. App. 21a-34a).

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ground that the corn was not adulterated within the meaning of 21 U.S.C. 342(a)(1) for its intended use. See 48 Fed. Reg. 53175 (1983); cf. J.A. 193, 194, 225.

[11] In September 1980, respondent Community Nutrition Institute (CNI) learned that North Carolina and South Carolina had sought exemptions, and the following month CNI urged the FDA to deny these requests and any similar ones. The FDA rejected CNI's request on November 28, 1980, in a letter giving the reasons for the agency's decision. J.A. 212-216.

Recognizing that an agency's interpretation of the statute it is responsible for administering is entitled to substantial deference, the court ruled that the FDA's construction of Section 406 was reasonable and that Section 406 "confers discretionary, not mandatory, authority on the agency to establish tolerances" (Pet. App. 31a-32a (footnote omitted)). The court also concluded that "action levels" were general statements of policy not requiring notice-and-comment rulemaking and that the exemptions granted by the FDA were within the agency's discretion (*id.* at 32a-34a).

2. *The Court Of Appeals' Decision.* The court of appeals reversed, holding that "the FDA may not proceed by means of action levels rather than tolerances" (Pet. App. 2a).[12] The court relied heavily on its parsing of the second clause of Section 406, which provides that when an added poisonous or deleterious substance is "required" or "cannot be * * * avoided * * * the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health." The court refused to accept (Pet. App. 6a) the FDA's interpretation of this provision, *i.e.*, that the Secretary is obligated to promulgate formal regulations only " 'to such extent as he finds necessary for the protection of public health' " and may employ informal action levels in all other circumstances. Instead, the court found (*id.* at 7a) that it was "clear from the structure of the sentence * * * that the phrase relied upon by the Secretary simply does not modify the pivotal word 'shall' " but, rather, "explains the standard that the Secretary is to employ in setting the tolerance."

The court of appeals found additional support for its interpretation of the FDCA in an argument that suggests that most of the nation's food supply is "adulterated" within the meaning of the FDCA. The court construed (Pet. App. 7a) Section 406 to mean that any food to which an unavoidable poisonous or deleterious substance

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[12] Because the court of appeals reversed on this ground, it did not consider respondents' other claims (Pet. App. 2a).

has been added is adulterated unless "a regulation establishing a tolerance is in effect." The court reasoned (Pet. App. 7a) that, "[s]ince the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." The court advanced no other argument to buttress its interpretation. It found "little guidance in the legislative history" (*id.* at 9a), and it did not cite any supporting judicial authority, but instead merely attempted to distinguish the cases upon which the FDA relied (*id.* at 11a-15a).

INTRODUCTION AND SUMMARY OF ARGUMENT

In the production of food, it is often impossible to avoid the presence of negligible quantities of added substances that may be harmful to human health if taken in sufficient amounts.[13] For nearly 50 years, the FDA, with Congress's full awareness and the federal courts' approval, has regulated the presence of these substances in food principally by adopting informal "action levels" —*i.e.*, "in-house" guidelines used by the agency to inform its broad prosecutorial discretion (see *Heckler* v. *Chaney*, No. 83-1878 (Mar. 20, 1985))—and by relying on these prosecutorial guidelines in case-by-case litigation under Section 402(a)(1) of the FDCA, 21 U.S.C. 342(a)(1). This informal procedure has allowed the FDA to move quickly in response to health hazards; it has provided flexibility in an area in which the relevant scientific data and the capabilities of good manufacturing

[13] See, *e.g.*, 42 Fed. Reg. 52814 (1977) ("[t]he Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities. This is not a modern phenomenon. Wholesome foods have inevitably been the carriers of levels of contamination beyond the capability of contemporary processing methods to eliminate and sometimes even detect. At best, therefore, specifications for 'food grade' substances can be established * * * to ensure that only minimal levels of contaminating substances are present."); J.A. 55.

practices are subject to frequent and unforeseen modification; and it has permitted the FDA, by limiting burdensome and lengthy formal rulemaking proceedings, to allocate its scarce resources to activities of greater need in safeguarding the public health.

In this case, the court of appeals ruled that the FDA's historic regulatory practice is—and has been from the outset—ultra vires. Relying entirely upon a literal reading of statutory language that is ambiguous at best, and without regard for the statute's legislative history or purposes, the court held that the FDA is powerless to follow its settled practice because it has a mandatory duty under Section 406, 21 U.S.C. 346, to institute formal rulemaking proceedings to establish tolerances for added substances like aflatoxin. That ruling upsets the FDA's settled and successful practice and threatens both to squander administrative resources and to impair the FDA's ability to act expeditiously in response to changing conditions in this vitally important area. The court of appeals' reasoning also suggests that much of the nation's food supply is now and will remain "adulterated" within the meaning of the FDCA until formal regulations setting tolerances are issued, a process that is certain to take years, if not decades, to complete.

These unfortunate consequences need not be suffered, because the court of appeals' decision is plainly wrong. The court disregarded the well settled principle that an agency's construction of a statute that it is entrusted to administer is entitled to substantial deference. Here, the FDA's construction of Section 406 is fully consistent with the language, structure, and purposes of that and related sections of the FDCA. Moreover, a number of factors coalesce to show that the FDA's interpretation of the Act is entitled to particular deference.

1. a. By focusing on the term "shall" in Section 406, the court of appeals misconstrued the overall structure of the FDCA. Section 402(a)(1) establishes the general standard of adulteration and provides that a food is adulterated whenever an added poisonous or deleterious

substance may render the food injurious to health. Sections 406 and 402(a)(2)(A) provide that such an added substance automatically renders a food adulterated if the substance is not required in food production or is not unavoidable. Where neither condition obtains, Sections 406 and 402(a)(2)(A) deem a food to be adulterated only if it contains a poisonous or deleterious substance in excess of an existing tolerance; if no tolerance exists, a food is adulterated only if it may cause injury under Section 402(a)(1). The language of Section 406 contemplates the situation in which no tolerance is in effect by providing that "[w]hile such a regulation is in effect * * * food [containing an added poisonous or deleterious substance] shall not * * * be considered to be adulterated" under Section 402(a)(1). See *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 166 (1958). In the absence of a tolerance, Section 402(a)(1) governs.

The court of appeals' reading of Section 406 renders Section 402(a)(1) superfluous for added poisonous or deleterious substances that are required in food production or unavoidable. Sections 406 and 402(a)(2)(A) ban added poisonous or deleterious substances if they are *not* required or are *not* unavoidable. Thus, if the absence of a tolerance also bans such substances if they *are* required or *are* unavoidable, the FDA would never have occasion to resort to Section 402(a)(1) to prove that a food that contains such a substance is adulterated, despite the fact that Section 402(a)(1), like Sections 406 and 402(a)(2)(A), applies to added substances. The FDA's construction of Section 406, unlike the one adopted by the court of appeals, therefore gives effect to Sections 402(a)(1) and 406 for added substances like aflatoxin.

b. The legislative background of Section 406 reveals that Congress enacted this provision to empower the agency to select alternative ways of proving that a food is adulterated. The predecessor to the FDCA (the Federal Food and Drugs Act of 1906) required the FDA to prove in court in each case that a particular food posed

a risk of injury to a consumer's health. *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914). Section 406 was designed to allow the agency to adopt legislative rules fixing precise levels of forbidden contaminants for a broad range of added substances that, if exceeded, automatically rendered a food adulterated. Congress did not intend that the FDA must promulgate tolerances to enforce the adulteration provisions of the FDCA; on the contrary, Congress retained the provision of the original Federal Food and Drugs Act that allowed the agency to prove on a case-by-case basis that a food containing an added substance was unsafe. Both the agency, which drafted the original version of the FDCA, and Congress used the verbs "shall" and "is authorized to" interchangeably throughout Congress's consideration of the FDCA. And no witness who testified during the lengthy legislative consideration of the FDCA suggested that tolerances would be the exclusive means of enforcing the food adulteration provisions of the Act.

2. The FDA's construction of Section 406 is entitled to special deference for several reasons. First, the agency played an important role in drafting the statute. Second, for nearly a half-century, beginning almost immediately after passage of the FDCA, the FDA has consistently read this section as providing the agency with the discretion to promulgate tolerances. Third, Congress has been made aware of the agency's position and has done nothing to require the FDA to alter its historic regulatory practice; in fact, Congress relied on the agency's views when enacting amendments to the FDCA. Fourth, depriving the FDA of the discretion whether to enforce the statute by relying upon action levels and bringing enforcement actions or by setting tolerances would hamper the agency's ability to respond quickly to new toxicological data or changes in manufacturing practices and would divert the agency's limited resources from matters of greater need in the protection of the public health.

ARGUMENT

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AUTHORIZES THE COMMISSIONER OF FOOD AND DRUGS TO REGULATE UNAVOIDABLE ADDED POISONOUS OR DELETERIOUS SUBSTANCES IN FOOD BY MEANS OF CASE-BY-CASE ADJUDICATION OR BY FORMAL RULEMAKING

It is a familiar and well-established principle of administrative law and statutory construction that an agency's interpretation of a statute that it is entrusted to administer is entitled to considerable deference from the courts. See, *e.g.*, *United States* v. *Riverside Bayview Homes, Inc.*, No. 84-701 (Dec. 4, 1985), slip op. 9; *Chevron U.S.A. Inc.* v. *NRDC*, No. 82-1005 (June 25, 1984), slip op. 4-7. A court is not free to overturn the agency's interpretation simply because the court may prefer a different one or because reasonable persons may differ as to the statute's meaning. Rather, so long as the agency has reasonably sought to implement a congressional policy rather than embark on a frolic and detour of its own, the agency's interpretation must be upheld. See, *e.g.*, *Riverside Bayview Homes*, slip op. 9-10, 17; *Chevron*, slip op. 5-7 & nn. 11-14; *Aluminum Co. of America* v. *Central Lincoln Peoples' Utility District*, No. 82-1071 (June 5, 1984), slip op. 8.

Under that standard, the FDA's contemporaneous and longstanding interpretation of Section 406 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346, should have been sustained. First, for the reasons given in Point A below, in light of the structure, purposes, and legislative history of the FDCA, it is entirely reasonable for the FDA to construe Section 406 as discretionary, rather than mandatory. Second, for the reasons explained in Point B below, a variety of factors make this a particularly compelling case for affording deference to the FDA.

A. The FDA's Interpretation of 21 U.S.C. 346 Is Consistent With The Text, Legislative History, And Purposes Of The Federal Food, Drug, And Cosmetic Act

As the court of appeals recognized, the pivotal statutory provision is the second clause of Section 406, 21 U.S.C. 346. It provides that when any added poisonous or deleterious substance is "required" in the production of food or "cannot be avoided by good manufacturing practice," the Commissioner of Food and Drugs "shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health." In the FDA's view, the phrase "to such extent as he finds necessary for the protection of the public health" modifies the verb "shall." So read, Section 406 provides that the agency must promulgate regulations only if it finds that doing so is necessary to protect the public health. Put another way, the statute means that the FDA *can* promulgate tolerances, not that the agency *must* do so. See *Webster's New Collegiate Dictionary* 1058 (1981) (noting these alternative definitions of "shall"). The FDA has long interpreted this section to mean that the agency is empowered, not required, to issue formal tolerances to enforce the adulteration provisions of the FDCA. See, *e.g.*, *Trade Correspondence* 136 (Mar. 7, 1940), *reprinted in* 1 V. Kleinfield, C. Dunn & A. Kaplan, *Federal Food, Drug, and Cosmetic Act Judicial Record 1938-1964*, at 622 (Food and Drug Law Inst. 1978).[14]

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[14] As the FDA there stated (emphasis added):

> The Administration, in the enforcement of old Food and Drugs Act, never announced formal tolerances for these substances in foods since no authority existed in the old law for so doing. The law * * * merely classified a food as adulterated if it contained any added deleterious ingredient which might render food injurious to health, leaving it a question of fact in each case that might arise as to whether the food was adulterated.
>
> We have, of course, as you know, informally announced certain tolerances for arsenic, fluorine and lead existing in

This Court also read the FDCA in that manner in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958). There, the Court examined the food adulteration provisions of the FDCA at issue in this case, Sections 402(a)(1) and 406(a) of the Act, 21 U.S.C. (1952 ed.) 342(a)(1) and 346(a), in the context of their relationship to the FDCA's color additive provisions, Sections 402(c) and 406(b), 21 U.S.C. (1952 ed.) 342(c) and 346(b).[15] The Court noted that "§ 406(a) [now 406] of the Act * * * *allows* the Secretary to establish tolerances for poisonous substances added to food where the substance is 'required in the production' of the food or 'cannot be avoided by good manufacturing practice'" (358 U.S. at 165-166 (emphasis added)) and found that "the provisions *authorizing* the establishment of tolerances apply only to § 402(a)(1) and (2) and do not apply to § 402(c)'s flat prohibition against the use of uncertified colors" (358 U.S. at 166-167 (emphasis added)). See *id.* at 166 ("Section 406(a) * * * provides for the system of tolerances"). Other courts have also concluded that Section 406 authorizes the agency to rely on either informal action levels or formal tolerances to enforce the adulteration provisions of the

spray residues on fresh fruits, these being 0.01 grain of arsenic per pound, 0.002 grain of fluorine per pound, and 0.025 grain of lead per pound. *The new Act* contains practically the same provision as indicated above but, *in addition, authorizes the Secretary to promulgate tolerances in the case of deleterious substances added to food where the addition cannot be avoided by good manufacturing practices or where such substance is required in the production of the food.*

[15] When *Flemming* was decided, Section 406 of the Act consisted of subsection (a) (which includes the current version of Section 406) as well as subsection (b), which provided: "[the FDA] shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors." Subsections (a) and (b) then in effect did share the common phrase "shall promulgate regulations," but subsection (b), unlike subsection (a), was not qualified by the phrase "to such extent as [the FDA] finds necessary for the protection of public health."

FDCA. See *United States* v. *Boston Farm Center, Inc.*, 590 F.2d 149, 151 (5th Cir. 1979); see also *Certified Color Industry Committee* v. *Secretary of HEW*, 236 F.2d 866, 868 (2d Cir. 1956); *United States* v. *Anderson Seafoods, Inc.*, 447 F. Supp. 1151, 1153 n.2 (N.D. Fla. 1978), aff'd, 622 F.2d 157 (5th Cir. 1980); *United States* v. *935 Cases, Etc., Tomato Puree*, 65 F. Supp. 503, 505 (N.D. Ohio 1946); cf. *United States* v. *Goodman*, 486 F.2d 847 (7th Cir. 1973). But see *United States* v. *Ewig Bros.*, 502 F.2d 715, 720 (7th Cir. 1974), cert. denied, 420 U.S. 945 (1975) (dictum).[16]

By contrast, the court below ruled that the Commissioner has the nondiscretionary duty to promulgate regulations governing every added substance before food containing the substances treated in Sections 402 and 406, 21 U.S.C. 342 and 346, may be shipped in interstate commerce and that the FDA may not enforce the FDCA by relying upon action levels. The court relied heavily on the dictionary meaning of what it termed "the critical word 'shall'" in the second clause of Section 406 (Pet. App. 6a), which the court construed as requiring the FDA to promulgate tolerances to exempt food containing any quantity of any unavoidable added poisonous or deleterious substance from the scope of that section (*id.* at 6a-7a). In addition, the court concluded that the phrase "to such extent as [the Commissioner] finds necessary for the protection of public health" modifies the participle "limiting," and thus affects the level of the

[16] Moreover, Section 306 of the FDCA, 21 U.S.C. 336, which permits the FDA "to refrain from prosecuting minor violations," has long been read to permit the FDA to employ action levels to implement the adulteration provisions of the Act. See, *e.g.*, *United States* v. *Boston Farm Center, Inc.*, 590 F.2d at 151; *United States* v. *Goodman*, 486 F.2d at 855; *United States* v. *Thriftimart, Inc.*, 429 F.2d 1006, 1011 (9th Cir.), cert. denied, 400 U.S. 926 (1970); *Dean Rubber Manufacturing Co.* v. *United States*, 356 F.2d 161, 164 (8th Cir. 1966); *United States* v. *1500 Cases More or Less, Tomato Paste*, 236 F.2d 208, 211-212 (7th Cir. 1956); *United States* v. *449 Cases, Containing Tomato Paste*, 212 F.2d 567, 572-573 (2d Cir. 1954); *United States* v. *133 Cases of Tomato Paste*, 22 F. Supp. 515, 516 (E.D. Pa. 1938).

tolerances that must be established rather than the FDA's discretion whether to adopt a tolerance at all. *Id.* at 7a. Accordingly, the court of appeals concluded that, in the absence of a formal tolerance, a food is adulterated if it contains any quantity of any substance specified in Section 406. Pet. App. 7a. We submit that the reasons offered by the court of appeals are plainly insufficient to overcome the FDA's settled construction of the Act.

1. *The FDA's Construction Of Section 406 Gives Effect To The Interrelationship Between Sections 402(a)(1) And 406*

Although the court of appeals properly began its analysis of the statute by looking to its plain terms (see *CPSC* v. *GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980)), the court went astray by focusing on the term "shall" in Section 406 to the exclusion of the statute as a whole. This Court has repeatedly explained that, "[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Philbrook* v. *Glodgett*, 421 U.S. 707, 713 (1975) (citation omitted); *Bob Jones University* v. *United States*, 461 U.S. 574, 586 (1983). By fixing exclusively on one possible interpretation of the literal meaning and placement of the term "shall" and failing to consider the relationship between Sections 402(a)(1) and 406, the court of appeals not only misconstrued Section 406, but also rendered Section 402(a)(1) superfluous for added substances, like aflatoxin.

a. *Section 406 Does Not Render Adulterated A Food Containing A Required Or An Unavoidable Added Poisonous Or Deleterious Substance In The Absence Of A Tolerance.* The starting point for analysis of the food adulteration provisions of the FDCA is Section 402, 21 U.S.C. 342, which establishes the general definition of "adulteration." Section 402 covers food containing either an added or an inherent substance. Since aflatoxin is an

added substance, only that portion of Section 402 applicable to added substances is directly relevant in this case.

Food containing an added poisonous or deleterious substance is deemed to be adulterated under Section 402 in two different situations.[17] First, under Section 402(a)(1), the food is adulterated if the substance is present in a sufficient quantity that the food may be injurious to health. 21 U.S.C. 342(a)(1). This section has been part of the federal food regulatory scheme since 1906, and it establishes a general, qualitative standard. Second, under Section 402(a)(2)(A), the food is adulterated if it is "unsafe" within the meaning of Section 406, 21 U.S.C. 346. 21 U.S.C. 342(a)(2)(A). Section 406 establishes a quantitative standard of adulteration.

The first sentence of Section 406 consists of two separate clauses, each of which covers a different situation. Under the opening clause of Section 406, the addition of a poisonous or deleterious substance to a food renders the food unsafe (and thus adulterated) if the substance is not required in the production of the food or is avoidable. The next clause of Section 406 addresses the alternative situation in which the addition of a poisonous or deleterious substance to food is required in food production or is unavoidable. In that circumstance, Section 406 renders a food unsafe if a tolerance is in effect and the food contains the added contaminant in an amount that exceeds the tolerance. Put another way, Section 406 bans the addition to food of a poisonous or deleterious substance when that substance is *not* required in food production or is *not* unavoidable. However, when the addition of a poisonous or deleterious substance to food *is* required in food production or *is* unavoidable, Section 406 does not automatically render unsafe food containing such a substance; only when the amount of that substance exceeds the level fixed by a tolerance is the food deemed to be adulterated.

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[17] Section 402(a)(2)(B) involves raw agricultural commodities containing pesticides, Section 402(a)(2)(C) involves food additives, and Section 402(a)(2)(D) involves new animal drugs. None of these sections is directly relevant to this case.

The first sentence of Section 406, then, does not directly address the circumstance in which a substance is required or unavoidable and a tolerance has *not* been established. However, the second sentence of Section 406 offers guidance as to how the statute operates in that situation. It provides that while a tolerance is in effect, a food containing an added poisonous or deleterious substance that is required in food production or is unavoidable is not deemed to be adulterated under Section 402(a)(1). The clear implication of this sentence is that Section 402(a)(1) *does* apply if no tolerance is in effect. In other words, the existence of a tolerance operates to exempt tainted food from the general adulteration standard found in Section 402(a)(1); in the absence of a tolerance, food is still subject to that section, under which a food is adulterated if it contains an added poisonous or deleterious substance "which may render [the food] injurious to health." The court of appeals therefore misread Section 406 by construing it to require the FDA to set tolerances for required or unavoidable added poisonous or deleterious substances in order to exempt food containing such substances from the automatic adulteration provisions of Sections 406 and 402(a)(2)(A).

Any other conclusion would be inconsistent with this Court's description of the statutory scheme in *Flemming* v. *Florida Citrus Exchange*, *supra*. There, the Court construed Section 406 to carve out specific exemptions from the adulteration provisions in Section 402(a)(1). As the Court explained, "[t]he existence of a tolerance is specifically stated in § 406(a) [currently 406] *only to give sanction to what would otherwise amount to adulteration within the terms of § 402(a)(1)*" (358 U.S. at 166 (emphasis added)). As this Court recognized, when no tolerance is in effect, Section 406 does not apply to added poisonous or deleterious substances that can be the subject of a tolerance; Section 402(a)(1) governs instead.

The court of appeals in essence read Section 406 as if it provides that food containing a required or unavoidable added contaminant is adulterated "unless" a tolerance is in effect. However, Section 406 does not contain that term, even though Congress knows how to draft a statute in that manner. Sections 408(a), 409(a), and 706(a) of the FDCA provide that pesticides, color additives, and food additives are deemed to be unsafe for purposes of Section 402(a)(1) "unless" there is a tolerance or exemption already in effect. See 21 U.S.C. 346(a) (pesticides); 348(a) (food additives); 376(a) (color additives). That difference cannot be attributed to mere legislative oversight; on the contrary, where "'Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion'" (*Russello* v. *United States*, 464 U.S. 16, 23 (1983) (citation omitted)). The court of appeals thus erred by failing to recognize that, in the absence of a tolerance, Section 406 does not render adulterated food containing required or unavoidable added contaminants.

b. *The FDA's Interpretation of Section 406 Gives Effect To The Role Played By Section 402(a)(1) In The Overall Regulatory Scheme.* It is a cardinal rule of statutory interpretation that a statute should be construed so as to give effect to all of its provisions. See, *e.g.*, *Dickerson* v. *New Banner Institute, Inc.*, 460 U.S. 103, 118 (1983); *American Textile Manufacturers Institute, Inc.* v. *Donovan*, 452 U.S. 490, 513 (1981). Here, the FDA's construction satisfies this precept, while the court of appeals' interpretation makes Section 402(a)(1) superfluous for "added" substances like aflatoxin, even though Section 402(a)(1) was expressly designed to play a role in their regulation.[18]

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[18] Section 402(a)(1) states, in part, that "*in case the substance is not an added substance* such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health" (emphasis added). This clause demonstrates that Section 402(a)(1) was meant to govern both added and inherent substances.

Under Section 406, the addition of a poisonous or deleterious substance automatically renders a food "unsafe" (and thus "adulterated" under Section 402(a)(2)(A)) if the added substance is not required in the production of food or can practicably be avoided. Therefore, it is undisputed that Section 402(a)(1) is not needed to regulate those substances. This obviously leaves only added substances that are required or unavoidable. As previously noted, the FDA's view is that it may regulate such added substances either by issuing action levels and bringing suit in appropriate cases under Section 402(a)(1) (in which case the FDA must prove in court that the added substance may render the food "injurious to health") or by promulgating regulations establishing tolerances under Section 406 (in which case any food exceeding those tolerances is automatically deemed to be unsafe and adulterated under Section 402(a)(2)(A)). See *Ciba Corp.* v. *Weinberger*, 412 U.S. 640, 643-644 (1973) (agencies may regulate by formal rulemaking or case-by-case adjudication); *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974) (same); *SEC* v. *Chenery Corp.*, 332 U.S. 194, 201-203 (1947) (same). The agency's interpretation assigns an important role to both Section 402(a)(1) and Section 402(a)(2)(A).

Under the court of appeals' construction, however, the FDA must issue regulations establishing formal tolerances for all required or unavoidable added contaminants. Once these tolerances are in effect, Section 402(a)(1) has no role to play: If a food is "unsafe" under Section 402(a)(2)(A) by virtue of a formal tolerance issued under Section 406, the FDA would have no need to proceed under Section 402(a)(1), which requires proof in court of a reasonable possibility of injury to health; on the other hand, if a food is deemed to be "safe" under such a tolerance, Section 406 expressly provides that the food "shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated" under Section 402(a)(1).

Furthermore, under the court of appeals' interpretation, if a tolerance is *not* in effect, a food is "unsafe" under Section 406 and thus adulterated under Section 402(a)(2)(A), once again leaving Section 402(a)(1) with no role to play. The court's construction of Section 406—rendering adulterated all food containing any required of unavoidable added contaminant, in the absence of a tolerance—thus would effectively eliminate from the FDCA the basic safety standard established by Section 402(a)(1) for all added substances.

Nor can the decision below be defended, as respondents suggest (Br. in Opp. 10), on the ground that Section 402(a)(1) will govern added substances whenever a new added contaminant is discovered until a tolerance is adopted. When Section 406 was enacted in 1938, the FDCA did not provide that Section 402(a)(1) would serve a transitional role until tolerances could be promulgated, although Congress has enacted other interim measures to serve that purpose. See, *e.g.*, the Color Additive Amendments of 1960, Pub. L. No. 86-618, § 203, 74 Stat. 404-407 (authorizing provisional listing of color additives). Moreover, respondents have identified nothing in the statute that would allow enforcement of the Act on a case-by-case basis, using action levels for newly discovered contaminants but not for long-recognized contaminants. And because Section 402(a)(1) does not set any transitional period, courts would be forced to engage in a standardless line-drawing exercise in order to determine when Section 402(a)(1) suddenly became ineffective and Section 402(a)(2)(A) came into play. There is no evidence indicating that Congress intended the FDCA to operate in this peculiar way. If the practical necessities of protecting the public health are an important consideration in the construction of the FDCA, as respondents appear to concede (Br. in Opp. 10), these matters are best left to the expert agency that Congress has entrusted with this responsibility.

2. *The FDA's Construction Of Section 406 Is Consistent With The Role That Provision Plays In The Enforcement Process*

As we have shown, the structure of 21 U.S.C. 342(a)(1) and 346 supports the agency's construction of the statute. Beyond that, the legislative background to the FDCA confirms that the agency's position is fully consistent with the role that Section 406 was meant to play in the enforcement process. Two laws are significant here: the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 *et seq.*, the first comprehensive federal food safety legislation, and the Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, which was the product of several years of intensive legislative study as both Congress and the FDA considered several different proposals to amend the 1906 Act. See generally C. Dunn, *Federal Food, Drug, and Cosmetic Act* (1938); Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 Law & Contemp. Probs. 2 (1939).[19] The background to Section 406, as reflected in these two statutes, reveals that the court of appeals misconstrued the purpose and effect of this section.

a. *The Federal Food and Drugs Act of 1906.* Section 7 of the 1906 Act stated that a food was adulterated if it contained "any added poisonous or other added deleterious ingredient which may render such article injurious to health." § 7 ¶ Fifth, 34 Stat. 770 (codified at 21 U.S.C. (1928 ed.) 8 ¶ "Food"). Within a decade of its enactment, this Court construed Section 7 to reach foods containing such an added substance if the food, "by any possibility," may injure the health of any consumer, "the strong and the weak, the old and the young, the well and the sick." *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, 411 (1914).

[19] Those portions of the legislative history pertinent to Sections 402(a)(1) and 406 are summarized in the appendix to the amicus curiae brief of the National Food Processors Association (at 1a-5a).

So construed, the 1906 Act provided a valuable instrument for protecting the public health. Nonetheless, the FDA concluded that additional enforcement powers would strengthen its hand in two ways. First, in an enforcement proceeding under the 1906 Act each food had to be considered by itself, and exposure to small amounts of the same poisonous or deleterious substance found in a variety of common foods in the diet could not be taken into account in a single proceeding.[20] In addition, unlike today, when federal agencies are often empowered to adopt regulations having the force and effect of law (see *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 295-298 (1979)), the Federal Food and Drugs Act of 1906 did not authorize the Department of Agriculture, the agency then responsible for enforcing that Act, to issue legislative rules defining categories of forbidden substances. The FDA had adopted informal standards for a number of added substances, such as pesticides.[21] But the FDA was required to prove in court on a case-by-case basis that a particular food was adulterated (see *United States* v. *Washington Dehydrated Food Co.*, 89 F.2d 606 (8th Cir. 1937)), a process that the agency

[20] See *Foods, Drugs, and Cosmetics: Hearings on H.R. 6906 et al. Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong., 1st Sess. 60 (1935) (Walter Campbell, Chief of FDA) [hereinafter cited as *1935 H.R. 6906 Hearings*]; *Foods, Drugs, and Cosmetics: Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 596 (1934) (Walter Campbell) [hereinafter cited as *1934 S. 2800 Hearings*]; *Foods, Drugs, and Cosmetics: Hearings on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong., 2d Sess. 19, 24 (1933) (Walter Campbell) [hereinafter cited as *1933 S. 1944 Hearings*].

[21] See, *e.g.*, *1933 S. 1944 Hearings* 22, 28 (Walter Campbell); Notice to Growers and Shippers of Fruits, Dep't of Agriculture (Apr. 2, 1933), *reprinted in 1933 S. 1944 Hearings* 219-220; Notice to Growers and Shippers of Fruits, Dep't of Agriculture (June 20, 1933), *reprinted in 1933 S. 1944 Hearings* 220; Notice to Growers and Shippers of Fruits, Dep't of Agriculture (Dec. 11, 1933), *reprinted in 1933 S. 1944 Hearings* 220; Cavers, *supra*, 6 Law & Contemp. Probs. at 2, 15; *Developments in the Law—The Federal Food, Drug, and Cosmetic Act*, 67 Harv. L. Rev. 632, 642 n.73 (1954).

had to repeat for each new substance and party. Accordingly, when Congress began its consideration of a successor to the 1906 Act, the FDA sought to add to its enforcement power by persuading Congress to grant the agency the discretionary authority to adopt legislative rules applicable to broad classes of contaminants.[22]

b. *The Federal Food, Drug, and Cosmetic Act of 1938.* The FDCA originated in the 73d Congress when the FDA, which drafted the original version of the Act,[23] submitted a bill (S. 1944, 73d Cong., 1st Sess. (1933)) to replace the 1906 Act. Section 10(a) of that proposal, according to Walter Campbell, Chief of the FDA, granted the agency quasi-legislative authority to establish tolerances setting precise levels of forbidden contamination.[24] This section—which FDA Chief Campbell called "an extremely important, in fact, one of the most important provisions of this bill" (*1933 S. 1944 Hearings* 18)—was intended to augment the agency's authority under the existing Act and *Lexington Mill* by empowering the FDA to make factual findings that took into account the range of poisons found in the diet and by allowing the agency to obviate the case-by-case adjudication then required to prove adulteration.[25] The bill submitted by the agency thus clearly provided an additional enforcement tool, not a substitute for its existing authority.

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[22] *1935 H.R. 6906 Hearings* 60 (Walter Campbell); *1934 S. 2800 Hearings* 596 (same); *1933 S. 1944 Hearings* 21, 80 (same).

[23] See *1934 S. 2800 Hearings* 572 (Walter Campbell).

[24] *1933 S. 1944 Hearings* 19 (Walter Campbell) ("[u]nder the terms of this bill the Secretary will be permitted to establish tolerances"); *id.* at 21 (same) ("[w]e are proposing here, in this and other sections of the act, to have authority conferred upon administrative officers to make certain findings of fact. * * * If this section of the bill were to be enacted there could be by executive action the establishment of legal tolerances for added deleterious ingredients"); *id.* at 22 (same) (noting that the public and business is benefitted if there is "some provision * * * for an administrative agency to be empowered on a fact finding basis to give expression to legislative intent").

[25] *1933 S. 1944 Hearings* 18-24, 28, 80-81 (Walter Campbell).

Although the court of appeals found that the verb "shall" in the current version of Section 406 of the FDCA was "critical" to a "common-sense" understanding of the meaning of this provision (Pet. App. 6a), neither the FDA nor Congress attributed any significance to this term; in fact, both the FDA and Congress used the verbs "shall" and "is authorized to" interchangeably. The bill drafted by the FDA used the verb "shall," yet the agency interpreted that bill as authorizing, not requiring, the agency to promulgate tolerances.[26] Senator Copeland, the sponsor of the bill drafted by the agency, stated that the proposal authorized the FDA to adopt tolerances.[27] The FDA consistently took the position during the congressional hearings on the various bills that the agency should be authorized, not required, to issue tolerances.[28] Some of the bills that Congress considered,

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[26] See S. 1944, 73d Cong., 1st Sess. § 10(a) (1933); page 28 note 24, *supra*; see also Annual Report of the Food and Drug Administration (1933), *reprinted at* C. Dunn, *supra*, at 25, 28.

[27] See 77 Cong. Rec. 5722 (1933) (Sen. Copeland) ("Memorandum on the Bill for Revising the Food and Drugs Act, Indicating Differences Between Bill and Present Law"); C. Dunn, *supra*, at 34.

[28] See *1933 S. 1944 Hearings* 19-21, 24, 80 (Walter Campbell); *id.* at 12 (Secretary of Agriculture Wallace) ("[t]he prohibition of added poisons in foods or the establishment of tolerances therefor is provided for"); *1934 S. 2800 Hearings* 596 (Walter Campbell); *Foods, Drugs, and Cosmetics: Hearings on S. 5 Before a Subcomm. of the Senate Comm. on Commerce*, 74th Cong., 1st Sess. 358 (1935) (Walter Campbell) [hereinafter cited as *1934 S. 5 Hearings*]; *1935 H.R. 6906 Hearings* 60, 96 (same). Other parties viewed these proposals in the same way. See *1933 S. 1944 Hearings* 108 (Dr. James Beal, National Drug Trade Conf.) ("Section 10 authorizes the Secretary to determine what added substances in food * * * 'is or may be injurious to health', and either to prohibit the use of such substances or to limit the amount which may be present."); *id.* at 374 (Statement Covering Senate Bill 1944, Kentucky State Board of Health (Dec. 1933)) ("[t]he proposed legislation authorizes the Secretary of Agriculture to establish, upon expert advice, safe tolerances for added poisons in food"); *id.* at 478 (Statement of California Fruit Exchange) (criticizing S. 1944 on the ground that it vests in the Secretary "complete authority to establish * * * tolerances").

such as the version drafted by the FDA, used the verb "shall" in connection with the provision that was ultimately to become Section 406 of the FDCA;[29] other bills used the term "is authorized to."[30] Nonetheless, each of the committee reports explaining these antecedents to Section 406, including the bill eventually enacted as that law, stated that it authorized the FDA to promulgate tolerances.[31]

Throughout the lengthy hearings on the Act, no one proposed that the term "shall" should be inserted into the Act to require the FDA to promulgate tolerances, no one argued that the case-by-case method of proving

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[29] See, *e.g.*, S. 1944, 73d Cong., 1st Sess. § 10(a) (1933); C. Dunn, *supra*, at 43; S. 5, 75th Cong., 3d Sess. § 10(a) (1938); Br. in Opp. 8-9. However, FDA Chief Walter Campbell, who was involved in the drafting of S. 1944, did not construe this term as requiring the FDA to establish tolerances. See *1933 S. 1944 Hearings* 13-28, 58-82. Moreover, following the 1933 Hearings on S. 1944, Senator Copeland, the sponsor of that bill, submitted a revised bill (S. 2000, 73d Cong., 2d Sess. (1933)), that substituted the term "is hereby authorized to" in place of the verb "shall" in Section 10(a) of S. 1944 without saying that he intended to change the substance of the bill. See *1933 S. 1944 Hearings* 493-494, 498. No one who testified on S. 1944 during the hearings stated that the term "shall" imposed a mandatory duty on the FDA to adopt tolerances. S. 5, 75th Cong., 3d Sess. (1938), also contained the term "shall," but no one in the House, where this substitution was made, maintained that this term imposed a mandatory duty on the FDA to promulgate tolerances. See pages 32-33, *infra*.

[30] See, *e.g.*, S. 2000, 73d Cong., 2d Sess. § 10(a) (1934); S. 2800, 73d Cong., 2d Sess. § 12(a) (1934); H.R. 8316, 73d Cong., 2d Sess. § 10(a) (1934); S. 5, 74th Cong., 1st & 2d Sess. § 304(a) (1935); S. 5, 75th Cong., 1st Sess. § 15(a) (1937); C. Dunn, *supra*, at 58, 78, 195, 646.

[31] See S. Rep. 493, 73d Cong., 2d Sess. 4 (1934) (accompanying S. 2800); S. Rep. 361, 74th Cong., 1st Sess. 6 (1935) (accompanying S. 5); S. Rep. 646, 74th Cong., 1st Sess. 3 (1935) (accompanying S. 5); H.R. Rep. 2139, 75th Cong., 3d Sess. 6 (1939) (accompanying S. 5); C. Dunn, *supra*, at 125, 249, 536, 554-555, 667, 820; see also 78 Cong. Rec. 8956 (1934) (Sen. Copeland). The bill (S. 5, 75th Cong., 3d Sess. (1938)) reported in H.R. Rep. 2139, *supra*, was the one ultimately adopted by Congress.

adulteration under *Lexington Mill* should be jettisoned in favor of exclusive reliance upon tolerances, and no one criticized the FDA for jeopardizing the public health by refusing to initiate enforcement proceedings. Rather, the controversy generated by the tolerance-setting features in these legislative proposals stemmed from the procedures by which the FDA would set tolerances, as well as the limited scope of judicial review available to a party seeking to have a tolerance set aside.

The apple industry, which used pesticides to control insect infestation, opposed the FDA's proposal to adopt tolerances for foodstuffs largely on procedural grounds. It complained that a tolerance could be set without the adversarial hearings required by the 1906 Act before a food could be deemed adulterated, and that judicial review was limited to the question whether a tolerance was arbitrary and supported by substantial evidence. Given the abbreviated administrative procedures necessary to set a tolerance,[32] the fact that a tolerance only required the government to prove that a specific level of contamination had been exceeded, and the narrow scope of judicial review, the apple industry claimed that the proposed tolerance provisions would radically alter the nature of

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[32] The original bill submitted by the FDA simply authorized the agency to promulgate tolerances and did not require the agency to follow any particular procedure in so doing. See Sections 10(a) and 23(a) of S. 1944, 73d Cong., 1st Sess. (1933), *reprinted at 1933 S. 1944 Hearings* 5, 10. More elaborate administrative procedures were devised during the course of the hearings in response to criticisms such as those voiced by the apple industry. See 78 Cong. Rec. 2728 (1934) (Sen. Copeland); *id.* at 4567 (same); *id.* at 8956 (same); Fuchs, *The Formulation and Review of Regulations Under the Food, Drug, and Cosmetic Act*, 6 Law & Contemp. Probs. 43, 46-48 (1939). For instance, in the bill that ultimately became the FDCA, the version passed by the Senate (and adopted by the House in a revised form) created a five member Committee on Public Health to serve in a consultative fashion and provided for a limited type of administrative hearing before a tolerance could be promulgated. See Sections 701-703 of S. 5, 75th Cong., 3d Sess. (1938), *reprinted at 1935 H.R. 6906 Hearings* 36-37.

criminal prosecutions for adulteration.[33] The industry's fear was that the substantive tolerance-setting provisions would shift to the defendant the burden of proof on the issue whether a food was adulterated, while the procedural aspects of these provisions (*i.e.*, dealing with the administrative issuance of a tolerance and subsequent judicial review) would emasculate the defendant's ability to prove that the agency's judgment was wrong. Authorizing the FDA to set tolerances vested undue power in its hands, the industry argued, which could be exercised in an arbitrary manner.

In response, the House of Representatives amended the Senate bill (S. 5, 75th Cong., 3d Sess. (1938)) to accommodate the concerns of the apple industry while still s' ngthening the FDA's hand. The House imposed elab- te administrative requirements before a tolerance could b. issued and rewrote the judicial review features of the bill, §§ 701-703, in order to subject a tolerance to exacting administrative and judicial scrutiny before it could become effective.[34] However, the House bill still empow-

[33] See, *e.g.*, *1933 S. 1944 Hearings* 204-210 (Samuel Fraser, Int'l Apple Ass'n); *id.* at 210-220 (Brief of Int'l Apple Ass'n); *id.* at 270 ("Written Analysis of Copeland Bill," submitted by Donald Burke); *id.* at 298-299, 301 (John Hall, Flavoring Extract Mfrs. Ass'n); *id.* at 428-429 (J.W. Herbert, Pacific Northwest Fruit & Vegetable Industry); *id.* at 478 (Prepared Statement of Californ'a Fruit Exchange); *1934 S. 2800 Hearings* 417-452 (Samuel Fraser); *id.* at 220- (Prepared Statement of Flavoring Extract Mfrs.); *1935 S. 5 Hearings* 254-276 (Samuel Fraser); *1935 H.R. 6906 Hearings* 323-336 (R.G. Phillips, Int'l Apple Ass'n); *id.* at 441-443 (Rep. Buck).

[34] H.R. Rep. 2139, 75th Cong., 3d Sess. 9-12 (1938) (describing revisions); *id.* Pt. 2, at 1-4 (Minority Views); *id.* at 3-4 (letter from Secretary of Agriculture Wallace to Rep. Mapes criticizing the review process); 83 Cong. Rec. 7772 (1938) (Rep. Robertson); *id.* at 7775-7776 (Rep. Lea); *id.* at 7783 (Rep. Leavy); *id.* at 7893 (Rep. Robertson); *id.* at 7894 (Rep. Voorhis); *id.* at 7894-7895 (Rep. Leavy); see generally *id.* at 7891-7898 (debate over proposed amendment to judicial review provisions of the FDCA, Sections 701-703 of S. 5, *supra*); Cavers, *supra*, 6 Law & Contemp. Probs. at 20-21; see pages 6-7, *supra* (describing regulatory and judicial review procedures). Some members of the House, which imposed

ered the FDA to issue tolerances. Although the House substituted the verb "shall" for the term "is authorized to" in Section 406(a) of the Senate bill, which granted the FDA the authority to set tolerances, the House did not modify the substance of that section. The House Report described Section 406(a) as authorizing, not requiring, the agency to issue tolerances. See H.R. Rep. 2139, *supra*, at 6 (emphasis added): "This subsection first prohibits the unnecessary addition of poisons. Where such additions are necessary, the establishment of tolerances is *authorized*, based upon the practical necessities for the use of poisonous substances." Moreover, both supporters and opponents of the elaborate administrative and judicial procedures in Sections 701-703 of S. 5, *supra*, agreed that, in regard to Section 406(a), "[t]his bill provides that the Secretary of Agriculture shall have the *authority* after proper hearing to prescribe the extent of spray residue that shall be permissible" (83 Cong. Rec. 7774 (1938) (Rep. Lea) (emphasis added)), and that, "[i]f enacted, this bill would give [the FDA] the *right* after proper hearings to adopt regulations prescribing limits [on pesticide residues]" (*ibid.* (emphasis added)).[35]

In sum, as one contemporary observer noted, "[t]he section defining the Secretary's powers [under Section 406(a)] was constantly revised during the evolution of the measure, but in the end did not greatly differ from

these requirements, stated that they believed these procedures were required by this Court's then-recent decision in *United States* v. *Morgan*, 304 U.S. 1 (1938). See 83 Cong. Rec. 9096, 9098 (1938) (Rep. Lea).

[35] See also 83 Cong. Rec. 7774 (1938) (colloquy between Reps. Sirovich and Lea); *id.* at 7775 (Rep. Lea) ("[i]n this bill we give a broad extension of authority to the Secretary of Agriculture, and in that respect it is one of the broadest bills ever passed by this Congress in ordinary peacetimes"); *id.* at 7784 (Rep. Coffee) ("[t]here is nothing radical or revolutionary about the sections in S.5, which authorize the Secretary of Agriculture to issue a regulation concerning * * * the amount of lead and arsenic which will be permitted on apples shipped in interstate commerce"); *id.* at 9097 (Rep. Lea) ("regulations may be established under this bill"); *id.* at 9100 (Rep. Reece).

that in S. 1944 [the original bill drafted by the FDA]. The major battle arising from this provision was fought on the issue of judicial review * * *." Cavers, *supra*, 6 Law & Contemp. Probs. at 27.

c. *The Effect Of Section 406.* The foregoing discussion demonstrates that the court of appeals misapprehended the import of Sections 402(a)(1) and 406 of the FDCA. As noted, the court of appeals' decision is bottomed in part on its belief that, in the absence of a tolerance, the presence in food of any amount of a required or an unavoidable added poisonous or deleterious substance violates the law, even if the level of that substance in food cannot pose any danger to human health. However, the FDCA has never incorporated that concept of adulteration. This Court squarely rejected that proposition in *Lexington Mill* in construing the predecessor 1906 Act, ruling that an added poisonous or deleterious substance must present a reasonable possibility of injury to the public health before the Act comes into play. See 232 U.S. at 410-411; page 26, *supra*. In the FDCA, Congress retained the prohibition in Section 7 of the 1906 Act, interpreted in *Lexington Mill*, forbidding any "added substance" in food that is poisonous or deleterious and that "may render it injurious to health" (§ 402(a)(1), 21 U.S.C. 342(a)(1)), thereby making clear that it intended to retain the substance of the 1906 Act as that law had been construed by this Court. S. Rep. 493, 73d Cong., 2d Sess. 3 (1934); S. Rep. 361, 74th Cong., 1st Sess. 6 (1935); cf. *Lorillard* v. *Pons*, 434 U.S. 575, 580-581 (1978).[36] The Court recognized in *Flemming* v.

[36] Walter Campbell made this precise point when he testified before Congress in 1934. *1934 S. 2800 Hearings* 530. In his words, the language in the pending legislation (that became the FDCA) (*ibid.*):

> is the language of the present law. That language has been considered in litigation which was carried to the Supreme Court, and has been very exhaustively discussed by that Court.
>
> Now, one of the concerns that we have is, first, the most extensive and most effective protections to the public that can be made. Unquestionably the use of the subjunctive provides that. And, second, to preserve the use of language which has already been considered by the Supreme Court.

Florida Citrus Exchange, *supra*, that the interpretation of "adulteration" adopted in *Lexington Mill* was carried forward into the current version of the FDCA, stating that "[t]he language involved in *Lexington Mill* survived generally in the Act's broadest and most general test of food adulteration, § 402(a)(1)." 358 U.S. at 161.

The court of appeals also erred by construing Section 406 as imposing a mandatory duty on the FDA to promulgate tolerances. The legislative history of Section 406 shows that it was designed to arm the FDA with the power to establish tolerances for the variety of foods in which a common poison was required or unavoidable so that the agency could employ an *additional* enforcement weapon against the interstate shipment of adulterated food. The FDA drafted the original version of this section to obtain discretionary authority to promulgate tolerances; Congress used the terms "shall" and "is authorized to" interchangeably when considering the FDCA; and no one challenged that interpretation of these bills. The sole opposition to the tolerance-setting provisions centered on the concern that the FDA would adopt tolerances too readily, not that the agency would fail to issue such regulations. In sum, by reading Section 406 as requiring the FDA to promulgate tolerances in order to exempt a food containing a required or unavoidable added contaminant from being adulterated, the court of appeals stood Section 406 on its head.[37]

[37] Respondents argue (Br. in Opp. 10) that the FDA's construction of the FDCA makes Section 406 superfluous, on the ground that Section 701 authorizes the agency to promulgate regulations to enforce the Act and thus presumably would empower the FDA to establish tolerances in the absence of Section 406. But Section 406 does far more than simply authorize the FDA to establish tolerances; it also provides that a food is not adulterated under Section 402(a)(1) if a tolerance is in effect, even if the FDA could prove in court that the food was potentially harmful. Furthermore, the legislative history of the FDCA shows that Section 406, not Section 701, was designed to provide the substantive standard by which the FDA was empowered to issue tolerances.

It is, in addition, extremely significant that the FDA did not contemporaneously interpret the bill adopted by the House as requiring the agency to set tolerances. The agency did not object to the House amendment to S. 5 on that ground (see H.R. Rep. 2139, *supra*, Pt. 2, at 3-4 (Minority Report) (reprinting letter from Secretary of Agriculture Wallace to Rep. Mapes criticizing the amendments made by the House Committee)); nor did the FDA immediately promulgate tolerances to exempt contaminated food from the scope of the newly-enacted Section 406, which would have been the obvious and necessary response to Congress's imposition on the FDA of the duty to do so. Moreover, if the court of appeals' construction of Section 406 were correct, then the members of the apple industry, who had opposed the grant of an unreviewable tolerance-setting authority to the FDA, would have become outlaws on the day the FDCA went into effect, since no tolerances had yet been promulgated permitting them to use pesticides. Finally, to our knowledge, no member of Congress ever criticized the FDA for failing to undertake the duty that the court of appeals found sprang into being once the FDCA became effective. That is powerful evidence that Congress never imposed any such duty in the first place.

B. The FDA's Longstanding Construction Of The FDCA Is Entitled To Substantial Deference

The structure, purpose, and legislative background of the FDCA thus provide substantial support for the agency's construction of Section 406. Beyond that, a variety of factors at work here present a powerful case for deference to the FDA. The FDA played an important role in drafting the statute (see *Miller* v. *Youakim*, 440 U.S. 125, 144 (1979)); the interpretation at issue involved a contemporaneous construction of the statutory language (see *Udall* v. *Tallman*, 380 U.S. 1, 16 (1965)); the FDA has consistently adhered to that construction for nearly 50 years (see *Zenith Radio Corp.* v. *United States*, 437 U.S. 443, 450 (1978)); Congress has never expressed its

dissatisfaction with the FDA's regulatory approach despite making revisions to related provisions of the FDCA (see *United States* v. *Rutherford*, 442 U.S. 544, 554 n.10 (1979)); in fact, Congress expressly noted and relied upon the agency's views when enacting those modifications (see *Riverside Bayview Homes, Inc.*, slip op. 13-15); and, of course, Sections 402 and 406 are central portions of a complex regulatory scheme that the FDA is charged with administering (see *Central Lincoln*, slip op. 8).

1. *The FDA Has Followed An Unwavering Construction Of 21 U.S.C. 342 And 346 Since The Inception Of The FDCA Nearly A Half-Century Ago*

For almost 50 years, the Secretary has consistently and publicly interpreted the FDCA as providing the FDA with the discretion to select between informally adopted action levels or formal tolerances to prevent the distribution of adulterated foods in interstate commerce. The FDA took this position from the outset, stating that Section 406 "authorized" the agency to promulgate tolerances. See *Trade Correspondence* 136 (Mar. 7, 1940), *reprinted in* 1 V. Kleinfield, C. Dunn, & A. Kaplan, *supra*, at 622 (page 17 note 14, *supra*).[38] The agency has also adhered to this position to the present. In 1974, for instance, in proposing regulations to govern the decision when formal tolerances should be promulgated, the agency stated explicitly that, under the Act, "[t]he Commissioner is not required to establish a tolerance for every added poisonous or deleterious substance * * *." 39 Fed. Reg. 42745. Three years later, the FDA issued regulations setting forth guidance as to when the FDA would proceed by formal tolerances rather than by action levels. See 21 C.F.R. 109.6(b) and (c). These regulations are neces-

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[38] See also *Trade Correspondence* 5-A (Nov. 5, 1945), *reprinted in* 1 V. Kleinfield, C. Dunn, & A. Kaplan, *supra*, at 751 (emphasis added) ("a tolerance *may* be fixed by regulation"); *Trade Correspondence* 3-A (Nov. 5, 1945), *reprinted in* 1 V. Kleinfield, C. Dunn, & A. Kaplan, *supra*, at 750 (stating that the FDA would not take action against apples and pears containing not more than 7 milligrams of DDT per kilogram of fruit).

sarily premised on and manifest the agency's belief that it had not been precluded by Congress from selecting between these alternatives. And the decided cases acknowledge that the FDA has relied on action levels in enforcing the food adulteration provisions of the FDCA. See, *e.g.*, *United States* v. *Boston Farm Center, Inc.*, *supra*; *United States* v. *Goodman*, *supra;* pages 18-19, *supra.* The agency's historic and unwavering interpretation of Section 406 is therefore entitled to substantial deference. See *Chevron*, slip op. 5-7; *Rutherford*, 442 U.S. at 553-554.

To be sure, the court of appeals' literal reading of the statute is not irrational. The word "shall," Justice Cardozo once wrote for the Court, "is the language of [a] command" (*Escoe* v. *Zerbst*, 295 U.S. 490, 493 (1935)). But he also made clear that the plain meaning of this term was "not controlling", because the courts must consider "a view of the ends and aims" of the legislation under consideration (*ibid.*). Here, the court of appeals did not deny that the FDA's interpretation of the statutory language was entirely rational and plausible. Nor did the court find that the agency's interpretation of the Act was foreclosed by its legislative history, created internal inconsistencies in the overall structure of the FDCA, produced anomalous results that Congress could not have intended, or created a regulatory loophole threatening the public health. The dictionary meaning of the term "shall" therefore provides no basis for overriding the agency's historic interpretation of a statute that it has been entrusted by Congress to administer, especially in view of the statute's obvious complexity. See *Pattern Makers* v. *NLRB*, No. 83-1894 (June 27, 1985), slip op. 19; *Chemical Manufacturers Ass'n* v. *NRDC*, No. 83-103 (Feb. 27, 1985), slip op. 8. As the Court has remarked, the FDCA must "be treated as a working instrument of government and not merely as a collection of English words." *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943). Since the FDA's construction of Section 406 implements the Act in this manner, the

statute should not be construed to defeat the agency's longstanding interpretation.[39]

2. *Congress Has Endorsed The FDA's Construction Of The FDCA In Amending The Act*

Longevity is not the sole factor militating in favor of the FDA's construction of the FDCA. The FDA's interpretation is entitled to enhanced deference because Congress specifically noted the agency's position while considering revisions of the FDCA and did nothing to alter that administrative practice. See, *e.g.*, *Haig* v. *Agee*, 453 U.S. 280, 297-298 (1981); *Chemehuevi Tribe of Indians* v. *FPC*, 420 U.S. 395, 410 (1975); *NLRB* v. *Gullett Gin Co.*, 340 U.S. 361, 366 (1951). Indeed, the legislative history of 21 U.S.C. 346a, which was adopted to modify Sections 402(a)(1) and 406, shows that Congress approved and relied upon the agency's position.

Under the FDCA, pesticides in food were originally governed by Section 406, 21 U.S.C. 346. However, in 1954 Congress enacted a new statute, 21 U.S.C. 346a, to regulate the presence of pesticide residues in raw agricultural commodities.[40] During the congressional hearings

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[39] The court of appeals also found that its construction of Section 406 was compelled by the structure of that provision. Pet. App. 7a. But even if the court believed that its own reading of the statute corresponded with the most refined rules of grammar, that too is an insufficient reason for refusing to defer to the agency's interpretation. Complex regulatory statutes are frequently written in a language that is all their own, and adherence to the strictest grammatical standards is not always a reliable way to divine Congress's intent (see *Flora* v. *United States*, 362 U.S. 145, 150 (1960) ("[t]his Court naturally does not review congressional enactments as a panel of grammarians")). Congress's use and placement of the word "shall" therefore simply marks the beginning of the inquiry, not the end.

[40] Section 346a(b) provides in pertinent part (emphasis added):

> The Administrator [of EPA] *shall promulgate regulations establishing tolerances* with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally

on this legislation, both the Commissioner of Food and Drugs and industry representatives expressly called to Congress's attention the FDA's position on the meaning of Section 406.[41] Thereafter, the agency's construction

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recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, *to the extent necessary to protect the public health.*

[41] The FDA Commissioner, Charles W. Crawford, stated (*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 4277 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 1st Sess. 121 (1953)):

> We have given out so-called informal tolerances on a great many of these things, we have freely given that out and if their schedules bring those spray residues within those informal tolerances there is no basis under the law for us to proceed because if we proceed on the other provision of section 402 [21 U.S.C. 342]—that is 402(a)(1) [21 U.S.C. 342(a)(1)], we have to assume the burden of proving that the quantity of the spray residue present in this particular commodity here in and of itself may injure the health of consumers and we would not give a tentative tolerance at a figure where there was any likelihood of our being able to make a case of that kind.

The National Canners Association wrote to both the House and Senate committees to express its understanding that Section 408 (21 U.S.C. 346a) would apply only to raw agricultural commodities. The Association's letter to the House committee stated (*Federal Food, Drug, and Cosmetic Act: Hearing on H.R. 7125 Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong., 2d Sess. 31 (1954) (emphasis added)):

> It is the understanding of the National Canners Association that after passage of this bill processed foods will be in exactly the same position as before in that *tolerances for pesticide residues with respect to processed foods may be established under section 406* [21 U.S.C. 346] *of the Act*; that in the event the Secretary acts to establish a tolerance for residues on processed foods under section 406 actions for adulteration will be taken under section 402(a)(2) *but if the Secretary has not acted under section 406 any action for adulteration because of excessive pesticide residue in the processed food will still be taken under section 402(a)(1)* [21 U.S.C. 342(a)(1)]. This understanding of the canning industry is, we are advised, shared by Dr. Miller [*i.e.*, Representative Miller, the sponsor of

not only was expressly noted without objection by both the House and Senate committees, but also appears to have played an important part in their thinking. See H.R. Rep. 1385, 83d Cong., 2d Sess. 2, 3, 6-7 (1954); S. Rep. 1635, 83d Cong., 2d Sess. 2, 3, 6-7 (1954).

For instance, the House Report, in describing the existing law, noted that when an added poisonous or deleterious substance is required in food production or practically unavoidable, "a tolerance *may* be established by the Secretary" (H.R. Rep. 1385, *supra*, at 2 (emphasis added)). The House Report also recognized that the FDA from the outset had adhered to and implemented its position that Section 406 was discretionary, observing that, while the law "authorizing" the issuance of formal tolerances had been in effect for more than 15 years, "[d]uring all that time control has been exercised through unofficial and informal tolerances" (*ibid.*). The House Report continued (*id.* at 2-3) that in 1950 "lengthy public hearings," costing nearly $500,000, had been held for the purpose of establishing official tolerances for pesticide residues in fresh fruits and vegetables but that official tolerances still had not been promulgated due to "the cumbersome, time-consuming, and impracticable procedure prescribed by existing law." To overcome these difficulties, the House committee recommended "an improved procedure for establishment of tolerances for pesticide chemicals remaining in or on raw agricultural commodities" (*id.* at 2). And to implement this goal, Section 3 of the Act ultimately adopted (Act of July 22, 1954, ch. 559, 68 Stat. 511 *et seq.*), according to the House Report, "gives to the Secretary * * * the *authority* to establish tolerances" (H.R. Rep. 1385, *supra*, at 8). The

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the House bill], by the FDA, and by all others interested in this legislation.

See also *Residues of Pesticide Chemicals: Hearing on S. 2868 and H.R. 7125 Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 83d Cong., 2d Sess. 93 (1954) (NCA letter to the Senate committee chairman to the same effect).

Senate Report made the identical points. See S. Rep. 1635, *supra*, at 2, 3, 6, 8.

Thus, the congressional committees expressly observed that the FDA was relying chiefly on informal rather than formal tolerances, yet they did not suggest that this practice was unlawful or undesirable, and they did nothing to require its abandonment in favor of exclusive reliance on formal rulemaking. On the contrary, both committees sharply criticized the formal statutory procedure set out in the FDCA and crafted a new, simpler, and speedier method for rectifying the problem caused by the breakdown of the formal procedure in the field of pesticide residues on raw agricultural commodities. Beyond that, although the statute Congress adopted provides that "[t]he Administrator shall promulgate regulations establishing tolerances * * * to the extent necessary to protect the public health" (21 U.S.C. 346a(b); see pages 39-40 note 40, *supra*), both the House and Senate Reports expressly described this provision as authorizing, not mandating, the adoption of formal tolerances, much as Congress had done when it adopted Section 406 of the FDCA. See H.R. Rep. 1385, *supra*, at 8; S. Rep. 1635, *supra*, at 2, 3, 6, 8.[42]

[42] Nor is this the only instance in which the FDA brought its construction of Sections 402 and 406 to Congress's attention. In the hearings preceding the adoption of the Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 *et seq.*, the FDA submitted a section-by-section analysis of the bill, stating that Section 102(a) "makes explicit, with regard to color additives, the interpretation of the Supreme Court in *Flemming* * * * that section 406(a) of existing law—which *authorizes* the establishment of tolerances for poisonous or deleterious substances added to food * * * —cannot serve as a basis for allowing the use of coal tar colors." *Color Additives: Hearings on H.R. 7624 and S. 2197 Before the House Comm. on Interstate and Foreign Commerce*, 86th Cong., 2d Sess. 27 (1960) (emphasis added). The House Report on the Act quoted the agency's analysis verbatim. See H.R. Rep. 1761, 86th Cong., 2d Sess. 69 (1960). In the hearings on the Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 *et seq.*, the agency once again informed Congress of its view on the meaning of Section 406. See *Food Additives: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 85th Cong., 2d Sess. 41 (1958) (letter from Secretary of HEW Folsom to Sen. Harris) ("[a]t present, under section 406(a) of the [FDCA], the Secretary is authorized to limit the poisonous or deleterious substances required in the production of food to such extent as he finds it necessary for the protection of public health").

The history of these amendments to the FDCA shows beyond question that Congress endorsed the FDA's interpretation of the statutory provisions at issue. As the Court has made clear, "once an agency's statutory construction has been 'fully brought to the attention of the public and the Congress,' and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned." *Rutherford*, 442 U.S. at 554 n.10. Indeed, here, Congress did more than decline to disturb the FDA's views; it actually incorporated those views into the new statute. Cf. *Riverside Bayview Homes*, slip op. 15; *Bob Jones University*, 461 U.S. at 601-602.

3. *The Court Of Appeals' Ruling Hampers The Effective Enforcement Of The FDCA*

Respondents have not suggested, and the courts below did not find, that the 20 ppb action level set by the FDA for aflatoxin does not adequately protect the public health, that formal tolerances are essential to prevent the interstate shipment of adulterated food, or that the FDA is not satisfactorily enforcing the FDCA. Nor did respondents offer any evidence to support such a claim. In fact, the historical record reveals that the FDA has vigorously enforced Section 402(a)(1) against added contaminants in food.[43]

[43] For a sampling of the FDA's enforcement efforts, see, *e.g.*, *United States* v. *Boston Farm Center, Inc.*, *supra* (FDA obtained an injunction prohibiting the marketing of aflatoxin-contaminated corn); *Seabrook Int'l Foods, Inc.* v. *Harris*, 501 F. Supp. 1086 (D.D.C. 1980), aff'd *sub nom. Continental Seafoods, Inc.* v. *Schweiker*, 674 F.2d 38 (D.C. Cir. 1982) (FDA issued a prohibition against importation of salmonella-contaminated Indian shrimp); *United States* v. *Anderson Seafoods, Inc.*, *supra* (FDA obtained an

The court of appeals no doubt assumed that its construction of the FDCA would contribute to the effective enforcement of the Act. Cf. *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (noting that the FDCA should be liberally construed in order to protect the public health); *Dotterweich*, 320 U.S. at 284 (same).[44] Quite the contrary is true, however. Unless reversed, the court of appeals' decision will have a significant adverse impact on the administration of the Act.

First, and most important, formal tolerances, once set, may retard the FDA's ability to respond quickly to new scientific findings or improvements in manufacturing processes that make it practicable to reduce the level of adulterants. See 21 C.F.R. 509.6(b)(3). Unlike other statutory provisions authorizing the emergency ban of pesticides (see 7 U.S.C. 136d(c)(3)) or drugs (see 21 U.S.C. 355(e)) found to pose an imminent hazard to the public health, the FDCA makes no provision for either

injunction prohibiting the marketing of mercury-contaminated swordfish).

The decided cases, of course, represent only a tiny fraction of the FDA's use of action levels to prevent the distribution of adulterated food in interstate and foreign commerce. Sections 702 and 704 of the FDCA, 21 U.S.C. 372 and 374, authorize the Commissioner to conduct inspections and to take and analyze food samples to determine whether they are adulterated. Each year, in accordance with instructions issued to its field offices, the FDA analyzes approximately 10,000 articles of domestically produced and imported food. The FDA thereafter recommends judicial enforcement actions only if the agency cannot obtain voluntary compliance by the person involved. Litigation therefore is the last step in the FDA's enforcement efforts and is necessary only on rare occasions.

[44] The court of appeals may have made this assumption because of its belief that any amount of aflatoxin "may render [food] injurious to health" under Section 402(a)(1). Pet. App. 4a. However, the only evidence of record on this point shows that food must contain at least 20 ppb aflatoxin in order to present any reasonable possibility of harm. See J.A. 193, 194, 225. Moreover, for certain uses, corn must contain more than 100 ppb aflatoxin before it may become injurious to health. See pages 9-10 note 10, *supra*.

the emergency revocation of a tolerance or the emergency condemnation of food meeting a tolerance. Once a formal tolerance is in effect, a food that does not exceed that tolerance is automatically deemed to be safe and unadulterated under Sections 402(a)(2)(A) and 406, 21 U.S.C. 342(a)(2)(A) and 346. Moreover, Section 406 provides that the food may not then be considered to be adulterated within the meaning of Section 402(a)(1)—even if the government could prove in court that the food may be "injurious to health." Thus, if a formal tolerance is issued and it is later discovered that the limit is too high, foods that satisfy the formal tolerance but that may in fact be unsafe according to the latest scientific studies will still be considered safe and unadulterated under the FDCA until the lengthy process of issuing a new, lower tolerance can be completed.[45]

Second, the court of appeals' reading of the statute would impose a severe administrative burden on the FDA and require the reallocation of scarce resources from activities of far greater utility in protecting the public health. Although the FDA originally expected that the authority to adopt tolerances would prove to be a valuable addition to the agency's enforcement arsenal, the exacting administrative and judicial review process

[45] This point is graphically illustrated by the FDA's experience with formal tolerances for polychlorinated biphenyls (PCBs). Based on newly obtained toxicological data, the FDA in April 1977 proposed to lower the existing tolerance from 5 parts per million (ppm) to 2 ppm for residues of PCBs in fish, shellfish, and several other classes of food. 42 Fed. Reg. 17487. The final rule was promulgated in 1979. 44 Fed. Reg. 38330. At the request of a fishing industry trade association, a hearing was held in May 1981. The FDA issued its decision in March 1982. 47 Fed. Reg. 10079. After the agency invited the submission of other relevant material (*ibid.*), the final decision was issued in May 1984. 49 Fed. Reg. 21514. During all this time, the 5 ppm tolerance remained in effect, thereby exposing consumers to levels of PCBs that the FDA considered potentially harmful. The entire process of lowering the tolerance for PCBs in fish and shellfish took seven years, although a comparable amendment of an action level could have been effected in a relatively brief period.

imposed by Congress in Section 701, 21 U.S.C. 371 largely defeated the agency's hopes. Despite showing some initial promise,[46] the tolerance-setting procedures, the FDA has learned, are often protracted and can seriously hamper the agency's ability to respond quickly to new developments.[47] Congress, too, has found that the formal rule-

[46] For example, in 1944 the FDA's predecessor agency took only four months to adopt a tolerance for fluorine spray residues on apples and pears. 9 Fed. Reg. 4654 (1944) (notice of hearing); *id.* at 9754 (proposed regulation); *id.* at 11836 (final order).

[47] This point is also illustrated by the adoption of formal tolerances for PCBs in paper materials used in packaging foods. In March 1972, the FDA proposed to establish formal tolerances for PCBs in food and paper food-packaging materials. 37 Fed. Reg. 705. In July 1973, the FDA published a final rule based on the proposal. 38 Fed. Reg. 18096. At the request of several paper industry firms a public hearing was granted. 40 Fed. Reg. 11563 (1973). Subsequently, the FDA's Bureau of Foods and the industry parties reached a proposed settlement agreement, which was submitted for the Commissioner's approval in November 1978. After further proceedings, a revised settlement agreement was announced in the *Federal Register* in August 1983. 48 Fed. Reg. 37020. Thus, the promulgation of a formal tolerance—where there was an objection but, by mutual agreement, no full trial-type hearing—took more than a decade to complete.

Respondents suggest (Br. in Opp. 13) that the formal rulemaking requirements of 21 U.S.C. 371(e) are not burdensome for the agency because the FDA can invoke the summary judgment procedures upheld in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973). That procedure may alleviate some of the congestion that is likely to ensue if the court of appeals' judgment is upheld, but it does not fully remedy the problem. FDA summary decisions can be, and have been, set aside by the courts. See, *e.g.*, *Hynson*, 412 U.S. at 622-623; *American Cyanamid Co.* v. *FDA*, 606 F.2d 1307 (D.C. Cir. 1979); *Edison Pharmaceutical Co.* v. *FDA*, 513 F.2d 1063 (D.C. Cir. 1975). Moreover, because the question in a tolerance-setting proceeding is the appropriateness of the level selected by the FDA, which requires the agency to consider the overall economic impact of that level (see 21 C.F.R. 509.6(b)(1); 42 Fed. Reg. 52816 (1977)), there is no reason to assume that objectors would not be able to raise genuine and substantial factual issues, which would prevent the FDA from granting summary judgment. (Indeed, respondent Public Citizen's Health Research Group was recently able to raise such issues in the context of, and to obtain a hearing

making procedures set forth in Section 701(e) are "cumbersome, time-consuming, and impracticable." S. Rep. 1635, *supra*, at 2; H.R. Rep. 1385, *supra*, at 3.

Nonetheless, court of appeals' decision would mandate such proceedings for numerous substances. The FDA currently has 21 action levels for eight added substances that could be regarded as within the scope of Section 406.[48] These substances can contaminate foods such as red meat, fish, milk and dairy products, eggs, corn, and wheat. See J.A. 150, 156, 165, 166, 167. Since a different action level may be necessary for each of several human foods and animal feeds, a given substance can require several action levels. Therefore, a tolerance-setting proceeding under Section 701(e) might likewise include a number of tolerances for each substance, depending on the food or feed involved. The greater the number of foods or feeds considered, the more complicated and time consuming the proceeding would be. The decision below, at the least, would seem to require that each of the FDA's current action levels be replaced by a formal tolerance.[49]

on, the FDA's final rule permanently listing a particular color additive for general use in food and in ingested drugs. See 40 Fed. Reg. 51145-51146 (1973) (notice of hearing).) In any event, there is no reason to assume that the extended litigation that would follow from an affirmance of the court of appeals' judgment would enhance the FDA's current ability to protect the public health, and respondents offered no evidence below that would justify such a conclusion.

[48] The FDA action levels to which Section 406 could now apply are: aflatoxin, cadmium, crotolaria seeds, mercury, nitrosodimethylamine (NDMA), paralytic shellfish toxin, polybrominated biphenyls (PPBs), and PCBs.

[49] Moreover, the logic of the court of appeals' decision is not limited to those substances for which an action level has already been set but rather extends to the whole universe of added, unavoidable poisonous or deleterious substances in food. Many of these substances may occur only in negligible amounts in a multitude of foods for which there is no existing action level; many of these substances, although undetectable using currently-available analytical methods, may be found in a variety of foods as such methods

Of course, the burden of establishing tolerances through the formal rulemaking process is not a sufficient reason for failing to do so if Congress required the FDA to regulate in this manner. But the FDA has found that the establishment of formal tolerances does not protect the public health to any significant degree beyond that afforded by its reliance on informal action levels. The FDA has long viewed the decision whether to establish formal tolerances as largely a question whether doing so will enhance its ability to enforce the food adulteration provisions of the FDCA by obviating the need to prove in court on a case-by-case basis that a certain food may present a danger to the public health by virtue of the particular level of a specific contaminant that it contains. Given the negligible addition to its enforcement power resulting from the establishment of tolerances, and the risk that their adoption might reduce (or, in some cases, eliminate) the flexibility necessary to respond to changed circumstances, the FDA has found that formal tolerances are not currently essential to its regulatory mission. There is *no* evidence that Congress disagrees with FDA's considered view, which represents precisely the type of scientific and policy judgment that Congress commonly entrusts to the administrative agency responsible for enforcing a complex regulatory scheme. See *Heckler* v. *Chaney*, No. 83-1878 (Mar. 20, 1985), slip op. 10; *Chevron*, slip op. 5-7. Construing the FDCA to require the FDA to adopt formal tolerances in these circumstances would hinder rather than promote the Act's purpose of protecting the public health by needlessly diverting the agency's limited resources from matters of more urgent public concern.

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become more sensitive; and many of these substances may yet be undiscovered. Aflatoxin, for example, was not discovered until the early 1960s. J.A. 34. But under the court of appeals' interpretation of Section 406, every one of these substances must be regulated by a formal tolerance, and every proposed modification of a tolerance must go through the same prolonged rulemaking process.

Finally, the reasoning of the court of appeals casts a cloud over the legality of large portions of the nation's food supply. As noted above, the court of appeals was under the mistaken belief that unless a formal tolerance has been issued any food containing an added, unavoidable poisonous or deleterious substance must be considered to be adulterated. Pet. App. 15a. Because many segments of the food supply now contain such substances (albeit in safe amounts), the necessary implication of the court's reasoning is that this food is "adulterated" within the meaning of 21 U.S.C. 342(a)(2)(A) and that persons responsible for growing, processing, or distributing it in interstate commerce are in violation of 21 U.S.C. 331 and are subject to an injunction (see 21 U.S.C. 332), seizure of the food (see 21 U.S.C. 334), or even criminal penalties (see 21 U.S.C. 333). For those potentially affected, it is cold comfort that the government would exercise its enforcement discretion in a fair and reasonable manner. See 21 U.S.C. 336; *Heckler* v. *Chaney*, *supra*. The affected parties ought not to be subjected to that risk in the absence of far clearer evidence than the court of appeals was able to muster that Congress intended the regulatory process to be structured in an entirely different fashion.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX

STATUTORY AND REGULATORY PROVISIONS INVOLVED

1. Section 402(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 342(a), provides:

A food shall be deemed to be adulterated—

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and

the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

2. Section 406 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346, provides:

> Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

3. Section 701(e) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(e), provides:

> (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.
>
> (2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor,

and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

4. 21 C.F.R. 509.6(b)-(c) provides:

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacuring practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account

the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level shall cease to be enforced and shall be revoked when a tolerance for the same substance and use has become effective.

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